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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/506,078	02/16/00	CAMPOS M	PC10202A

023913
PFIZER INC
235 E 42ND STREET
NEW YORK NY 10017

HM12/1227

EXAMINER	
FOLEY,S	
ART UNIT	**PAPER NUMBER**
1648	6

DATE MAILED: 12/27/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary	Application No.	Applicant(s)	
	09/506,078	CAMPOS ET AL.	
	Examiner	Art Unit	
	Shanon A. Foley	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 February 2000* is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15)☒ Notice of References Cited (PTO-892)
16)☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other: .

DETAILED ACTION

Drawings

The drawings are objected to because there are figures for 6D, 7D, 8D, 9D, and 12C, but no description of the drawings in the specification.. Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 11, 13, and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3, 13, and 16 are drawn to inhibiting the endogenous activity of a native protein in a vertebrate. The claims are drawn to any peptide, which is not enabled by the scope of the claimed invention.

Claim 11 seems to have the proteins of portion (a) and (b) reversed. In claim 1, portion (a) of the fusion protein is identified as the peptide that is endogenously synthesized in the vertebrate, but in claim 11, portion (a) is derived to protect against infection by a pathogen. Portion (b) in claim 1 is identified as an immunogen from a pathogen, but in claim 11, (b) is designated as the endogenous protein.

Claim 11 recite "the fusion protein is derived in a vertebrate which endogenously synthesizes the peptide which can be pathogenically infected by the pathogen". The protein is infected by the pathogen?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Der Zee et al. in U.S. Patent 5,684,145 and Mittal et al.

The claims are drawn to a fusion protein producing a dual immune response in a vertebrate that comprises a first proteinaceous portion that is GnRH, the activity of this peptide is to be inhibited within the vertebrate. The second portion of this peptide is the immunogenic glycoprotein D (gD) from BHV-1. These proteins are encoded by a polynucleotide in a vector that is expressed in a transformed cell. A dual-function vaccine that comprises the fusion protein or the vector inhibits the activity of endogenous GnRH, which includes inhibiting the sexual characteristics in a cow and protects against BHV-1.

Van Der Zee et al. teaches a recombinant DNA molecule that codes for a hybrid protein comprising GnRH that is conjugated to *E. coli* fimbrial-filiments in a vaccine and elicits an immune response against GnRH. This recombinant DNA molecule is expressed in a microorganism, which equivalent in the art to the host cell claimed in the application. See the abstract, example 1 in columns 14-16, claims 1-8. Van Der Zee et al. teaches that previous attempts to completely elicit an immune response against GnRH have been unsuccessful due to the fact that GnRH itself is non-immunogenic and therefore needs a strong immunogenic carrier to elicit an effective immune response against GnRH, such as E. coli fimbrial-filiments that have

strong antigenic properties, see columns 2-5. In example 3, adult rats that were given the plasmid containing the hybrid protein showed serum antibody binding, which showed a disruption and suppression of estrous cycles, see Example 3, columns 16 and 17. Bulls that were immunized with the plasmid resulted in a reduction of scrotal growth compared to control animals, see example 4 in column 18. The teachings of Van Der Zee et al. do not include using gD from BHV-1 as the immunogenic component to the fusion protein.

However, Mittal et al. teaches that a full-length recombinant form (gD) and a truncated form of gD (tgD) from BHV-1 was inserted into a human adenovirus type 5 vector. The antigenicity of both proteins was found to be similar to native gD expressed in BHV-1 infected cells. The vaccine response in animals was better in the full-length form than tgD. Furthermore, after vaccine challenge, no infectious BHV-1 virions were isolated from the rats previously immunized with the full-length gD. See the abstract, figures 1, 3, 4, 5 and the discussion section.

One of ordinary skill in the art at the time the invention was made would have been motivated to combine the strong immunogenicity of gD taught by Mittal et al. with the teachings of Van Der Zee et al. that successfully evoked a complete immune response against GnRH when expressed with a strongly antigenic carrier in order to suppress the endogenous hormone and protect against disease. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention because the teachings of Van Der Zee et al. indicate that all that is needed to induce an immune response against GnRH is a strong immunogenic carrier, which is what gD from BHV-1 is from the teachings of Mittal et al. Therefore the invention as a whole is prima facie obvious to

one of ordinary skill in at the time the invention was made, as evidenced by the references, especially in the absence to evidence to the contrary.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon A. Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on 7:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley
December 23, 2000

MARY E. MOSHER
PRIMARY EXAMINER
GROUP ~~1800~~ 1600